

# Nivolumab Versus Cetuximab In Recurrent/Metastatic Squamous Cell Carcinoma Of The Head And Neck. A Real-World Data Study

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August 23, 2022

## Abstract

### Aim

Assess the effectiveness and safety of nivolumab versus cetuximab in patients with R/M HNSCC, as well as to analyze possible prognostic factors for response to treatment with nivolumab.

### Methods

We conducted an observational, retrospective, descriptive study of patients with R/M HNSCC who initiated treatment with nivolumab or cetuximab monotherapy in two periods of equivalent duration. Overall efficacy was measured in progression-free survival (PFS) and overall survival (OS); safety was evaluated using the CTCAE (Common Terminology Criteria for Adverse Events) classification version 5.0 of the National Cancer Institute (NCI).

### Results

Median overall survival (OS) was 9.1 months with nivolumab (n=34) vs. 6.3 months with cetuximab (n=12)(HR=0.5; 95%CI: 0.24-1.03; p=0.058). Progression free survival (PFS) were 4.3 for nivolumab and 4.65 months for cetuximab (HR=0.59; 95%CI: 0.29-1.19; p=0.14). Any grade adverse events (AEs) were reported in 97% and 100% of the patients treated with nivolumab and cetuximab. Serious AEs were observed in 26% and 58% of the patients respectively. Elevated albumin values, lymphocytosis, neutropenia and elevated neutrophil/lymphocyte ratio values have positive prognostic value on the response to nivolumab in R/M CCECC.

### Conclusion

Effectiveness of nivolumab in terms of OS remains superior to cetuximab. OS, PFS and severe or any grade AEs were superior in both arms of our study than in the clinical trials. The AEs profile of nivolumab differs in our study from the clinical trials' observations. We have identified four positive statistically significant prognostic variables on the response to nivolumab in R/M HNSCC.

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